

## REMARKS

Claim 26 has been amended to overcome various rejections discussed below, and now recites a method of administering insulin to the buccal mucosa by spraying an effective amount of insulin to the buccal mucosa with a metered dose inhaler, while resisting substantial inhalation. No new matter is added; support for the amendment can be found on page 8 of the specification, which describes how the formulation can be administered to the buccal region by ensuring that the person does not inhale the formulation as it is sprayed.

### Rejections under 35 USC § 112

Claims 26-37 have been rejected under 35 USC § 112, second paragraph, as being indefinite. According to the Examiner, recitation of “an effective amount” in Claim 35 is indefinite since effective amount is not defined in the claim. Applicant respectfully traverses this basis of rejection. As amended, for reasons discussed below, Claim 26 now includes this phrase. Claim 35 has been cancelled.

Applicant respectfully submits that one skilled in the art would be able to determine the effective amount, that is, the amount of insulin necessary to achieve the desired therapeutic result, which depends on the severity of the illness, the time of day the insulin is administered, and other various factors. The relationship between administration of insulin and blood glucose levels has been known for decades. The specification provides clear guidance on how to mix various amounts of insulin with the micelle formulation to achieve lower blood glucose levels, and comparative data for oral delivery of insulin as compared to injection. Applicant respectfully submits that the phrase “an effective amount” does not render Claim 26 indefinite and requests withdrawal of this basis of rejection.

Claims 26-37 have also been rejected under §112, second paragraph, and under §101 as improper method claims. As amended, Claim 26 and the claims depending therefrom properly describe a method of administering insulin to the buccal mucosa, by spraying the insulin with a metered dose inhaler while resisting substantial inhalation. Applicant respectfully submits that Claims 26-37 are no longer indefinite and requests withdrawal of this basis of rejection.

#### Rejections under 35 USC § 102

Claims 26-27 and 37 have been rejected under 35 USC § 102(e) as anticipated by Manning (US Patent No. 5,770,559). Applicant respectfully traverses this rejection. As amended, Claim 26 recites administration of an effective amount of insulin to the buccal mucosa, while substantially resisting inhalation. Manning does not teach or suggest delivery of an effective amount to the buccal mucosa, nor would an effective amount inherently be delivered with the method of Manning. Manning also does not teach or suggest administration of insulin while resisting inhalation; in fact, it teaches the opposite. Applicant respectfully submits that Claim 26, as amended, and Claims 27 and 37 are not anticipated by Manning and requests withdrawal of this rejection.

#### Rejections under 35 USC § 103

Claims 26-27, 29 and 37 have been rejected under 35 USC § 103(a) as being obvious in view of Manning or Radhakrishnan (US Patent No. 5,040,389), both of which are cited as teaching pulmonary delivery of insulin in micelles. Applicant respectfully traverses this rejection. The cited references do not teach or suggest aerosol delivery of an effective amount of insulin to the buccal mucosa while resisting inhalation, nor would an effective amount be inherently delivered with pulmonary administration. Applicant respectfully submits that Claim 26, as amended, and Claims 27, 29 and 37 are not obvious in view of Manning or Radhakrishnan and requests withdrawal of this rejection.

#### Double Patenting Rejection

Claims 26-37 have been provisionally rejected under the doctrine of obviousness-type double patenting as being unpatentable over Claims 26-35 of co-pending application 09/386,285. In the event the pending claims in the present application are allowed, Applicant will file a terminal disclaimer to obviate the double patenting rejection.

## SUMMARY

In view of the above amendment and remarks, Applicant submits Claims 26-34 and 36-37 are in condition for allowance; such action is respectfully requested at an early date.

Respectfully submitted,

A handwritten signature in cursive script, reading "Debra Z. Anderson", with a long horizontal flourish extending to the right.

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## APPENDIX

Additions are marked in bold; deletions are bracketed.

26. A method for administering insulin to the buccal mucosa **comprising spraying an effective amount of said insulin to the buccal mucosa** using a metered dose inhaler, **while resisting substantial inhalation of said insulin.**